Texas DSHS Austin TB Laboratory Testing Services

Laboratory Contact	Title	Phone Number	Email
Denise Dunbar	Manager, Mycobacteriology- Mycology	512-776-7342	denise.dunbar@dshs.state.tx.us
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TB Diagnostics Services:

AFB Smear
AFB Culture
Nucleic Acid Amplification Testing
Direct Testing by HPLC
Positive Culture Identification by HPLC

TB Reference Services:

Referred Isolate Identification
Positive Culture Identification by Accuprobe
First and Second Line Drug Susceptibility Testing of M. tuberculosis complex
Rifampin Susceptibility Testing of M. kansasii
Genotyping Submissions
Referral of M. tuberculosis complex isolates for CDC MDDR Testing
Special Test Referrals, other
Mycology

Setting up new submitter accounts

To request a new submitter account or to update an existing account, please use this link:

http://www.dshs.state.tx.us/lab/MRS_forms.shtm

When the page loads, please scroll down to the second table and the submitter account form can be down loaded by clicking "Submitter Identification (ID) Number Request Form".

After you complete this form, please fax it to Sandra Navarro at (512) 776-7533. If you have any questions about your submitter account, you can reach Sandra at 1-888-963-7111 ext. 2377. Sandra can also explain the options for receiving TB reports (reports can be received by FAX, Mail, or via the web portal).

A TB laboratory requisition form, the G-MYCO form, will be created for your facility and emailed to you. Please print off a new form for each specimen that is submitted. Hint: for consistency, a master form could be created for each patient and photocopied for each specimen submission. The only information that would be updated with each submission is the date of collection (and possibly the specimen type).

Ordering TB specimen containers

It is recommended that initial, diagnostic specimens be shipped overnight to our laboratory on cold pack. Follow-up specimens can be shipped using pre-paid USPS mailing labels and containers provided by our laboratory. To order the TB specimen containers, please use this link:

http://www.dshs.state.tx.us/lab/MRS_forms.shtm .

Scroll down to the table and click on the link for G-6F order form to order mailers for TB specimens. Once you download and complete the G-6F order form, please fax the order form to 512/776-7672 or you can email a scanned copy to containerprepgroup@dshs.state.tx.us . Please be sure to include your Submitter ID # on the order form. If you have any questions, contact the Container Preparation Group at 512/776-7661.

Signing up for Web Portal Access

For requesting a log in and password for the Web Portal), use this link: http://www.dshs.state.tx.us/lab/remoteData.shtm .

Scroll down to "Applying for Remote Data Systems Forms". Fill out and submit one Facility Security Agreement (PDF 20kb) per facility and one User Security Rights and Confidentiality Form (PDF 22kb) per remote user.

You need to provide your facility's name and address as you are registered with the DSHS Laboratory (as your information is listed on the physical result reports you receive from the Lab). You will need to provide the 8-digit DSHS Submitter Identification number you are submitting specimens under.

You may submit your completed forms by either of the methods below. Please do not submit the instruction sheets (Pg 2) of either form.

Fax: 512-776-7157, Attention Remote Lab Support
Email: Scan the forms to PDF and email to remotelabsupport@dshs.state.tx.us

Packaging Specimens for Shipping

For specimens being shipped by a courier such as FedEx or UPS, please contact the courier for packing instructions.

For specimens being shipped in DSHS pre-paid USPS mailing containers, please follow these instructions:

The requirements for the submission of Biological Substance, Category B through the U.S. Postal Services system are:

1. Definition: "Biological Substance, Category B means any human or animal material, including excreta, secreta, blood and its components, tissue, and tissue fluids being transported for diagnostic or investigational purposes."

2. Quantity: 50 ml or less per mail piece. Two or more primary receptacles may be included per mail piece.

3. Secondary container (plastic liner): must contain sufficient absorbent materials such as paper toweling to absorb the entire contents of primary containers in case of breakage or leakage.

4. Outer mailer: must be properly labeled.

   Mailing unit must pass current shipping regulations for Biological Substance, Category B.

The definition of an acceptable triple container is:

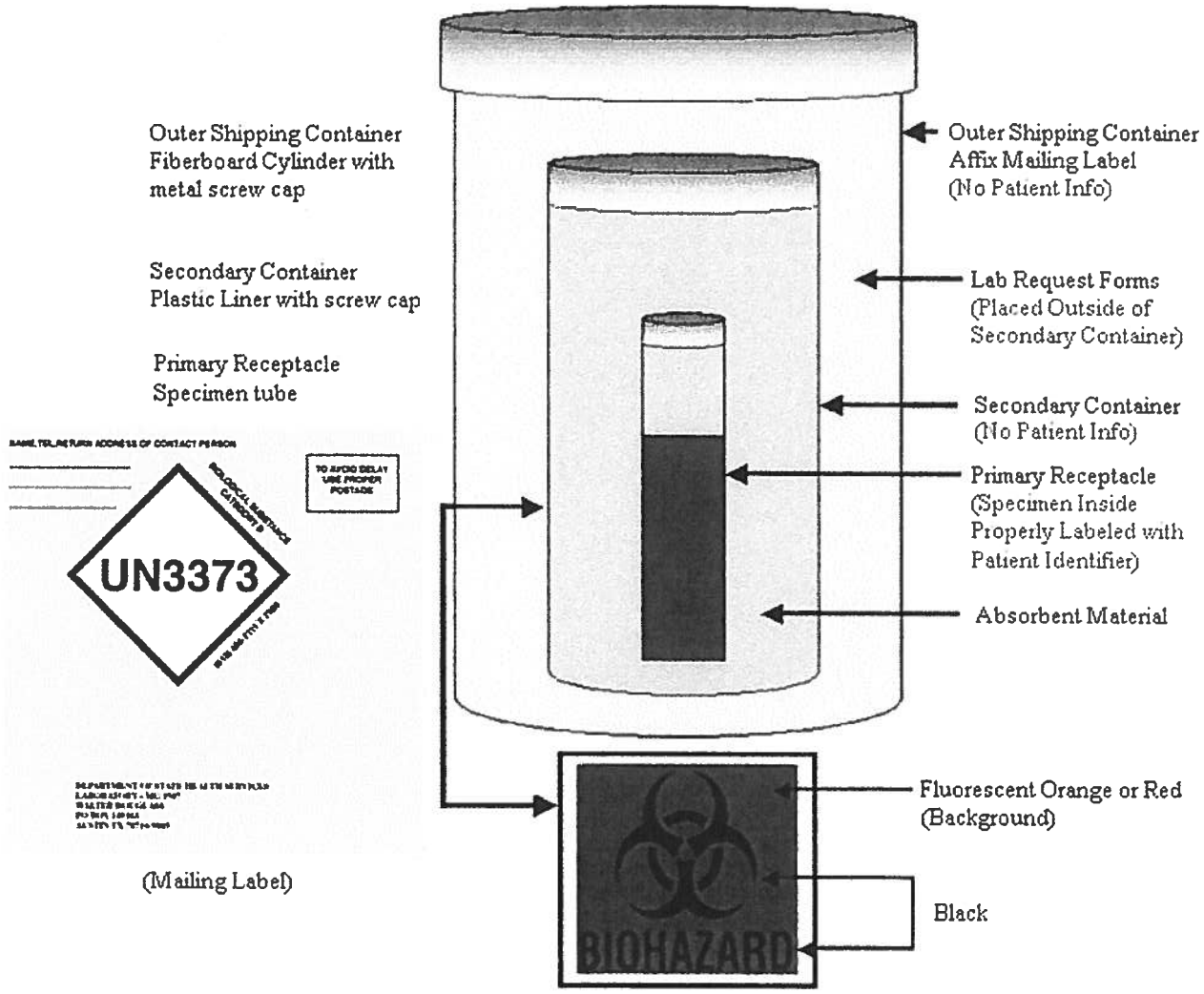
1. primary receptacle: a bottle or tube in which the specimen is collected or held, such as the 50 ml conical tube; leak proof and securely sealed; surrounded by absorbent material capable of taking up the entire contents of the primary receptacle(s); held within the secondary container; **The patient name must be labeled on the primary receptacle and must match the patient name on the G-MYCO form. Missing patient identifiers on the primary specimen container is the most common reason for specimen rejection.**

2. secondary container: leak proof, securely sealed; placed within the strong outer mailer; Biohazard sticker affixed;

3. outer mailer or container constructed of fiberboard or other equivalent material, clearly and durably marked "Biological Substance, Category B".

Packaging and Labeling Biological Substance, Category B

(Do not put any patient information on outer or secondary containers or lids.)



(Mailing Label)

Biohazard Label should be on Secondary Container.
DO NOT put Biohazard Label on Outer Container.

Completion of Specimen Submission Form, G-MYCO

- **TDSHS request form (*for AFB smear and culture, please use form G-MYCO*) must be included with every specimen in the same container.**

Forms should be completed as follows:

- Use **BOLD CAPITAL BLOCK LETTERS** to complete all information that is requested on the form.
- If the patient is Medicaid eligible, you **must** provide the Medicaid number.
- **Date of Birth, Date of Collection and test request are required.**
- For AFB smear and culture, the **specimen type is required.**
- **Unidentified or improperly identified specimens are unsatisfactory and they will not be tested.**

We will test specimens identified by number only; however, we will not report the results until a patient's name is provided. Good laboratory practice recommends, and our federal license requires, the patient's name on the specimen vial.

The patient's name on the specimen requisition form and the specimen must be the same.

If they are not the same, the specimen will NOT be tested.

- If your facility is contracted with the Texas DSHS TB Services Branch, please mark the Payor Source, Section 7. as TB Elimination. **If the Payor Source is not marked, your facility will be billed.**

TEXAS Department of State Health Services

Specimen Acquisition: (512) 776-7598

G-MYCO Specimen Submission Form (SEP 2013)

CAP# 3024401 CLIA #45D0660644

Laboratory Services Section, MC-1947
P. O. Box 149347, Austin, Texas 78714-9347
Courier: 1100 W. 49th Street, Austin, Texas 78756
(888) 963-7111 x7318 or (512) 776-7318
http://www.dshs.state.tx.us/lab

For DSHS Use Only
Place DSHS Bar Code Label Here

Section 1. SUBMITTER INFORMATION – (** REQUIRED)

Submitter/TPI Number **	Submitter Name **
NPI Number **	Address **
City **	State ** / Zip Code **
Phone **	Contact
Fax **	Clinic Code

Section 2. PATIENT INFORMATION -- (** REQUIRED)

NOTE: Patient name is REQUIRED & MUST match name on this form, Medicare/Medicaid card, & specimen container

Last Name **	First Name **	MI
Address **	Telephone Number	
City **	State ** / Zip Code **	Country of Origin / Bi-National ID #
DOB (mm/dd/yyyy) **	Sex ** / SSN	Pregnant? ☐ Yes ☐ No ☐ Unknown

Race: ☐ White ☐ Black or African American ☐ American Indian / Native Alaskan ☐ Asian ☐ Native Hawaiian / Pacific Islander ☐ Other

Ethnicity: ☐ Hispanic ☐ Non-Hispanic ☐ Unknown

Date of Collection ** (REQUIRED)	Time of Collection ☐ AM ☐ PM	Collected By

Medical Record #	ICD Diagnosis Code ** (1)	ICD Diagnosis Code ** (2)	ICD Diagnosis Code ** (3)

Section 3. SPECIMEN SOURCE OR TYPE -- (**REQUIRED)

- ☐ Abscess (site) _____
- ☐ Aspirate (site) _____
- ☐ BAL
- ☐ Biopsy (site) _____
- ☐ Blood
- ☐ Bone marrow
- ☐ Bronchial washings
- ☐ Cervical
- ☐ CSF
- ☐ Eye
- ☐ Feces/Stool
- ☐ Gastric
- ☐ Lesion (site)_____
- ☐ Lymph node (site)_____
- ☐ Nasopharyngeal
- ☐ Pleural fluid/PLF
- ☐ Sputum: Induced
- ☐ Sputum: Natural
- ☐ Thoracentesis fluid
- ☐ Tissue (site) _____
- ☐ Urine
- ☐ Vaginal
- ☐ Wound (site) _____
- ☐ Other: _____

Section 4. CLINICAL SPECIMEN

Is this specimen from an outbreak investigation? ☐ Yes ☐ No

Patient spends substantial time in a congregate setting (e.g. jail, homeless shelter)? ☐ Yes ☐ No

- ☐ AFB Smear Only (for release from Isolation)
- ☐ AFB Smear and Culture
- ☐ AFB Smear, Culture and Direct NAAT (Respiratory Diagnostic Specimens Only)
- ☐ AFB Smear and Blood Culture

FOR RESPIRATORY SPECIMEN, PROCESSED SEDIMENT:

- ☐ Direct NAAT for M. tuberculosis (NAAT ONLY – NO CULTURE PERFORMED)

Please provide the AFB smear result for this processed sediment: _____

Section 5. REFERRED PURE CULTURE

- ☐ Referred AFB Isolate Identification
- ☐ MTB Genotyping Only/for Compliance
- ☐ Fungal Isolate Identification
- ☐ Actinomycete, Aerobic, Identification

NOTES: Please see the form's instructions for details on how to complete this form.
Visit our web site at http://www.dshs.state.tx.us/lab/.
All dates must be entered in mm/dd/yyyy format.

Section 6. ORDERING PHYSICIAN INFORMATION – (** REQUIRED)

Ordering Physician's NPI Number **	Ordering Physician's Name **

Section 7. PAYOR SOURCE – (REQUIRED)

1. **Reflex testing** will be performed when necessary and the appropriate party will be billed.
2. If the patient does not meet program eligibility requirements for the test requested and no third party payor will cover the testing, **the submitter will be billed.**
3. Medicare generally does not pay for screening tests-please refer to applicable Third party payor guidelines for instructions regarding covered tests, benefit limitations, medical necessity determinations and Advanced Beneficiary Notice (ABN) requirements.
4. If Medicaid or Medicare is indicated, the Medicaid/Medicare number is required. Please write it in the space provided below.
5. If private insurance is indicated, the required billing information below is designated with an asterisk (*).
6. **Check only one box** below to indicate whether we should bill the submitter, Medicaid, Medicare, private insurance, or DSHS Program.

☐ Medicaid (2) ☐ Medicare (8)

Medicaid/Medicare #: _____

☐ Submitter (3) ☐ Private Insurance (4)
☐ BIDS (1720) ☐ Refugee (7)
☐ IDEAS (1620) ☐ TB Elimination (1619)
☐ Other: _____ ☐ Other: _____

HMO / Managed Care / Insurance Company Name *

Address *

City *	State *	Zip Code *

Responsible Party *

Insurance Phone Number *	Responsible Party's Insurance ID Number *
Group Name	Group Number

"I hereby authorize the release of information related to the services described here and hereby assign any benefits to which I am entitled to the Texas Department of State Health Services, Laboratory Services Section."
Signature of patient or responsible party.

Signature * Date *

Section 8. SUSCEPTIBILITY TESTING

Is MDR M. tuberculosis suspected? ☐ Yes ☐ No

Note: Drug susceptibility tests are performed automatically on patient's initial M. tuberculosis isolate.

☐ **MTB Primary Drug Susceptibility Panel**
- ☐ Ethambutol
- ☐ Isoniazid
- ☐ Pyrazinamide (PZA)
- ☐ Rifampin

☐ **MTB PZA Susceptibility Test Only**

☐ **MTB Agar Susceptibility Panel**
- ☐ Capreomycin
- ☐ Ethambutol
- ☐ Ethionamide
- ☐ Isoniazid
- ☐ Kanamycin
- ☐ Ofloxacin
- ☐ Rifabutin
- ☐ Rifampin
- ☐ Streptomycin

M. kansasii Susceptibility Test
- ☐ Agar, Rifampin

FOR LABORATORY USE ONLY Specimen Received: ☐ Room Temp. ☐ Cold ☐ Frozen

G-MYCO Specimen Submission Form Instructions

For mailing and specimen packaging information, visit DSHS Laboratory Services Section's web page at http://www.dshs.state.tx.us/lab/.

The specimen submission form ***must*** accompany each specimen.
The patient's name listed on the specimen ***must*** match the patient's name listed on the form.
If the Date of Collection field is not completed or is inaccurate, the specimen will be rejected.

Place DSHS Bar Code Label Here: Place the specimen bar code label that will be used to identify and track the specimen in the DSHS laboratory information management system (LIMS). If you are performing remote entry, place DSHS LIMS specimen bar code label here.

Section 1. SUBMITTER INFORMATION

All submitter information that is required is marked with double asterisks (**).

Submitter/TPI number, Submitter name and Address: The submitter number is a unique number that the Texas Department of State Health Services (DSHS) Laboratory Services Section assigns to each of our submitters. To obtain a Texas Provider Identifier (TPI) number, contact Texas Medicaid and Healthcare Partnership (TMHP) at 1-800-925-9126.

To request a DSHS Laboratory Services Section submitter number, a master form, or to update submitter information, please call (888) 963-7111 x7578 or (512) 776-7578, or fax (512) 776-7533 or visit http://www.dshs.state.tx.us/lab/mrs_forms.shtm#email.

NPI Number: Indicate the facility's 10-digit NPI number. All health care providers must use the National Provider Identifier (NPI) number. To obtain an NPI number, contact the National Plan and Provider Enumeration System (NPPES) toll free at (800) 465-3203 or via their web site at https://nppes.cms.hhs.gov/NPPES/Welcome.do.

Indicate the submitter's name, address, city, state, and zip code. Please print clearly, use a pre-printed label, or use a legible photocopy of a master form provided by the Laboratory Services Section.

Contact Information: Indicate the name, telephone number, and fax number of the person to contact at the submitting facility in case the laboratory needs additional information about the specimen/isolate.

Clinic Code: Please provide, if applicable. This is a code that the submitter furnishes to help them identify which satellite office submits a specimen and to help the submitter identify where the lab report belongs, if the submitter has a primary mailing address with satellite offices.

Section 2. PATIENT INFORMATION

Complete all patient information including date of collection, time of collection, last name, first name, middle initial, address, city, state, zip code, country of origin, telephone number, date of birth (DOB), date and time of collection, collected by, sex, social security number (SSN), pregnant, race, ethnicity, medical record number, and ICD diagnosis code.

NOTE: The patient's name listed on the specimen ***must*** match the patient's name listed on the form.

Information that is required to bill Medicare, Medicaid, or private insurance has been marked with double asterisks (**). These fields must be completed. You may use a pre-printed patient label.

Patient Name: If patient is covered by Medicaid, Medicare, or Private Insurance, the name on the specimen form and specimen must match the name on the Medicaid, Medicare, and insurance card, respectively.

Date of birth (DOB): Please list the date of birth. If the date of birth is not provided, the specimen may be rejected.

Pregnant: Indicate if female patient is pregnant by marking either Yes, No, or Unknown.

Date of Collection/Time of Collection: Indicate the date and time the specimen was collected from the patient or other source. Do not give the date the specimen was sent to DSHS. **IMPORTANT: If the Date of Collection field is not completed or is inaccurate, the specimen will be rejected.**

Collected By: Clearly indicate the individual who collected the specimen.

Medical Record # / Alien # / CUI: Provide the identification number for matching purposes. CUI is the Clinic Unique Identifier number.

Previous DSHS Specimen Lab Number: If this patient has had a previous specimen submitted to the DSHS Laboratory, please provide the DSHS specimen lab number.

ICD Diagnosis Code(s), Country of Origin (if applicable): Indicate the diagnosis code or findings that would help in processing, identifying, and billing of this specimen/isolate. If the patient's country of origin is not the U.S., then please provide the patient's country of origin.

Section 3. SPECIMEN SOURCE OR TYPE

Specimen Source or Type: Indicate the kind of material you are submitting or the source of the specimen or isolate. **For mycobacteriology specimens, complete this section or the specimen will be rejected.**

For tuberculosis treatment, a specimen source or type MUST be provided for specimens used for the diagnosis or monitoring of TB. *DO NOT leave this section blank.*

For specimens other than those listed, check the "Other" box and write in the site and source selected from the TB Elimination Division's list of Anatomic Sites and Corresponding Specimen Sources, which can be obtained from your local or regional health department.

Test Requested: You **MUST** check or specify the specific test(s) to be performed by the DSHS Laboratory Services Section. For specific test instructions, see the Laboratory Services Section Manual of Reference Services. To cancel a test that is marked in error on the form, mark one line through the test name, write "error", and initial.

Section 4. CLINICAL SPECIMEN

Outbreak/Surveillance (if applicable): Tell us whether the specimen/isolate is part of an outbreak or cluster. If the specimen is being submitted because of an outbreak, write in the associated name of the outbreak next to the outbreak box.

Patient spends substantial time in a congregate setting (e.g. jail, homeless shelter): Indicate whether or not this patient is in a congregate setting as this would be an indication for rapid direct testing of a diagnostic specimen.

AFB Smear and Culture will always be performed on clinical specimens being tested by NAA.

Direct NAAT Only testing will only be performed on the sediment remaining from the processed sediment. Culture must be in progress in the submitting laboratory. Please provide the AFB Smear result obtained by the submitting laboratory.

Section 6. ORDERING PHYSICIAN INFORMATION

Ordering Physician's Name and NPI Number: Give the name of the physician and the physician's NPI number. **This information is required to bill Medicaid, Medicare, and insurance.**

Section 7. PAYOR SOURCE

THE SUBMITTER WILL BE BILLED, if the required billing information is not provided, is inaccurate, or if multiple payor boxes are checked.

Indicate the party that will receive the bill by marking only one box.

Please do not use this form for THSteps or medical check-ups; use the G-THSTEPS form.

If selecting Medicaid or Medicare:

- Mark the appropriate box.
- Write in the Medicaid or Medicare number.
- If the patient name on the form does not match the name on the Medicaid/Medicare card, the submitter will be billed.
- Patient's DOB and address must be provided.

If selecting Private Insurance:

- Mark the appropriate box.
- Complete all fields on the form that have an asterisk (*).
- If the private insurance information is not provided on the specimen form or is inaccurate, the submitter will be billed.
- Patient's DOB and address must be provided.

If selecting a DSHS Program:

- If you are contracting and/or approved by a DSHS program to provide services that require laboratory testing, please indicate which program. For program descriptions, see the Laboratory Services Section's Manual of Reference Services located on the web site at http://www.dshs.state.tx.us/lab/prog_desc.htm.
- **Do NOT check a DSHS program as a Payor Source if the patient has Medicaid, Medicare, or private insurance.**
- For BIDS (Border & Infectious Disease Surveillance) or IDEAS, check the appropriate box. Please check the "Other" box and list the program's name in the space provided if necessary.

HMO / Managed Care / Insurance Company: Print the name, address, city, state, and zip code of the insurance company to be billed. If all insurance information is not provided on the specimen form, the submitter will be billed. NOTE: The DSHS laboratories are not an in-network CHIP or CHIP Perinate provider. If CHIP or CHIP Perinate is indicated, the submitter will be billed.

Responsible Party: Print the Last Name, First Name of the responsible party, the insurance ID number, insurance company's phone number, group name, and group number.

Signature and Date: Have the responsible party sign and date to authorize the release of their information, if DSHS is to bill their insurance or HMO.

Section 8. SUSCEPTIBILITY TESTING

Please note that initial isolates of *M. tuberculosis* complex from a new patient will automatically be tested against the primary drug susceptibility panel.

REFLEX & REFERENCE TESTING:

Please note that additional testing procedures (i.e., reflex testing) will be performed when necessary and clinically indicated by the initial lab test results. Reflex testing will be billed to the appropriate payor in addition to the original test requested. This is particularly applicable to microbiology testing and other laboratory testing requiring confirmation or further diagnostic work.

All reference tests will be billed to the submitter at the prevailing reference laboratory's price with the addition of a handling fee.

For specific test instructions and information about tube types, see the Laboratory Services Section Manual of Reference Services on our web site at http://www.dshs.state.tx.us/lab/.

Ordering Nucleic Acid Amplification Testing (NAAT)

When Should You Order NAAT on sputum?

There should be clinical suspicion of tuberculosis. NAAT should be requested if the test results will make a difference to the patient's treatment or if the test results will make a difference to the contact investigation.

Patient should not have a laboratory diagnosis of tuberculosis disease already.

NAAT is performed on both expectorated and induced sputum.

If the specimen is not sputum, or if you have any questions:

*****Telephone Denise Dunbar (512-776-7342) and Ken Jost (512-776-7580) or email denise.dunbar@dshs.state.tx.us and ken.jost@dshs.state.tx.us *******

Other Considerations:

For NAA T requests, it is recommended that initial, diagnostic specimens be shipped on cold pack for overnight delivery to our laboratory.

AFB Smear and Culture must be performed simultaneously with NAAT.

If the patient has been on TB medications for over a week, it is possible for the culture to be negative for *M. tuberculosis* and the NAAT may be positive for *M. tuberculosis*. The NAAT can detect non-viable *M. tuberculosis* in the specimen.

Consultation on case management is encouraged! Assistance with the management of TB patients may be requested from the State TB Nurse Consultant at (512) 533-3144.

Medical consultation from one of the Department of State Health Services (DSHS) recommended expert physicians is required if the patient's isolate is isoniazid and/or rifampin resistant. Consultation should also be requested if the patient remains symptomatic or continues to be AFB smear and/or culture positive after two months of treatment. The expert physicians can assist in determining the utility of rapid molecular testing arranged through our laboratory.

Medical consultation with a DSHS recommended expert physician is available through the Heartland National TB Center at 1-800-839-5864 or the Center for Pulmonary and Infectious Disease Control at 1-800 428-7432. Pediatric medical consultation is available with Jeffery Starke, M.D., Baylor College of Medicine at 1-832-824-4330.

Ordering Nucleic Acid Amplification Testing (NAAT)

How to Order NAAT on Sputum:

On the G-MYCO submission form, under Section 4, ONLY check test request "AFB Smear, Culture, and Direct NAAT (Respiratory Diagnostic Specimens Only)".

For private laboratories that perform AFB smear and Culture and are submitting the leftover sputum for NAAT Only, check test request "Direct NAAT for M. tuberculosis (NAAT Only – No Culture Performed).

Contacts for questions or consultation:

Denise Dunbar (512-776-7342) denise.dunbar@dshs.state.tx.us

Ken Jost (512-776-7580) ken.jost@dshs.state.tx.us

DSHS-Austin TB Testing Algorithm